

**REMARKS**

Claims 1–21 are pending in the application. Claims 9–17, 20, and 21 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as being drawn to a non-elected species. Claims 2–8 are rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 3, 5–7, 18, and 19 are rejected under 35 U.S.C. § 102(e). Claims 2, 4, and 8 are rejected under 35 U.S.C. § 103(a). Applicant respectfully traverses these rejections for at least the reasons stated below and respectfully requests the Examiner to reconsider and withdraw these rejections. Further, claims 1–7 are rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over claims 1, 3, 6–8, 10, and 11 of U.S. Patent No. 6,808,486.

In the Office Action, the Examiner further objected to the Specification and claims 2 and 18 based on various informalities. Applicant has amended the Specification and claims to correct these formalities and respectfully requests the Examiner to withdraw those objections.

**Objections to the Specification**

The Examiner objected to the disclosure because "at page 1, lines 4-6, the current status of the parent application should be provided." (Office Action, page 2). With this Reply, Applicant has amended the Specification to include issue information of the parent case. Accordingly, Applicant respectfully requests the Examiner to withdraw the objection to the Specification.

**Objections to the Claims**

The Examiner objected to claims 2 and 18 based on informalities and required appropriate correction. With this Reply, Applicant has amended claims 2 and 18 to correct the typographical errors pointed out by the Examiner. Accordingly, Applicant respectfully requests the Examiner to withdraw the objections to claims 2 and 18.

**Claim Rejections Under 35 U.S.C. § 112**

The Examiner rejected claims 2–8 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the

subject matter Applicant regards as the invention. In particular, the Examiner noted that in the dependent claims 2-8 it is unclear whether Applicant intends to claim the entire surgical instrument of independent claim 1 or only various subcombinations.

With this Reply, Applicant has amended claims 2-8 to claim the entire surgical instrument of independent claim 1. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of claim 2-8 under 35 U.S.C. § 112.

#### **Claim Rejections Under 35 U.S.C. § 102**

The Examiner rejected claims 1, 3, 5-7, 18, and 19 under 35 U.S.C. § 102(e) as allegedly being anticipated by Staskin et al., U.S. Patent Application Pub. No. 2003/0045774 ("Staskin"). Applicant respectfully traverses these rejections for at least the reasons stated below.

For a claim to be anticipated under 35 U.S.C. § 102, each and every claim limitation must be found within the cited prior art reference and arranged as required by the claim. M.P.E.P. § 2131.

Applicant respectfully asserts that Staskin does not disclose "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1 and similarly in claim 18. The Examiner cites Staskin at paragraph [0118] as allegedly "teaching a sling capable of being applied to an area beneath and supporting the urethra or bladder neck." (Office Action, p. 4). The Examiner does not specifically cite any passage of Staskin as teaching "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1 and similarly in claim 18. Accordingly, Applicant respectfully traverses this rejection.

Staskin instead discloses a sling that is "preferably rectangular for treating SUI in females . . . ." (Staskin, paragraph [0119], Fig. 4). This type of sling is commonly referred to as a "tape" sling. As discussed in the disclosure of the present application, such a design "do[es] not restore the normal anatomical relationship of the urinary bladder to the urethra." (Page 9, lines 9-10). By contrast, a contoured

sling as claimed "is shaped to restore the normal anatomy of the urethra and base of the bladder," which encourages normal voiding following incontinence surgery. (Page 9, lines 10–13). Further, in the present invention, the normal anatomical position is restored not only of the urethra, but also of the base of the bladder.

There is no language in Staskin that discloses a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder. Nor does Staskin disclose the desirability or importance of restoring the normal anatomical relationship of the urinary bladder to the urethra. Therefore, "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1 and similarly in claim 18, is not comparable to simply "a sling capable of being applied to an area beneath and supporting the urethra or bladder neck."

For at least the reasons stated above, Staskin does not disclose "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1 and similarly in claim 18. Therefore, Staskin does not disclose all of the limitations of claim 1, and thus Staskin does not anticipate claim 1. M.P.E.P. §2131. For at least the same reasons, Staskin similarly does not anticipate claim 18.

Claims 3 and 5–7 depend from claim 1 and are therefore not anticipated by Staskin for at least the same reasons stated above with reference to claim 1.

Claim 19 depends from claim 18 and is therefore not anticipated by Staskin for at least the same reasons stated above with reference to claim 18.

Applicant submits that claims 1, 3, 5–7, 18, and 19 are patentable over Staskin for at least the reasons stated above, and respectfully requests the Examiner to withdraw the rejections under 35 U.S.C. § 102(e).

#### **Claim Rejections Under 35 U.S.C. § 103**

The Examiner rejected claims 2, 4, and 8 under 35 U.S.C. § 103(a) as allegedly unpatentable over Staskin in view of various references. Specifically, claim 4 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Staskin in

view of Bilbo, U.S. Patent Application Pub. No. 2002/0103542 ("Bilbo"), and claims 2 and 8 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Staskin in view of Inman et al., U.S. Patent Application Pub. No. 2003/0065246 ("Inman"). Applicant respectfully traverses these rejections for at least the reasons stated below.

**A. Claim 4 is not properly rejected under Staskin in view of Bilbo.**

Claim 4 is patentable over Staskin for at least the reasons discussed above with respect to claim 1.

As discussed above, claim 1 is patentable over Staskin at least because Staskin does not disclose "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1. Bilbo does not cure this defect because Bilbo also does not disclose "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1.

Claim 4 depends from claim 1. Therefore, claim 4 also contains the limitation "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1. Thus, claim 4 is patentable over Staskin in view of Bilbo for at least the reasons discussed above.

**B. Claims 2 and 8 are not properly rejected under Staskin in view of Inman.**

**1. Claims 2 and 8 are patentable over Staskin for at least the reasons discussed above with respect to claim 1.**

As discussed above, claim 1 is patentable over Staskin at least because Staskin does not disclose "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1. Inman does not cure this defect because Inman also does not disclose "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1.

Claims 2 and 8 depend from claim 1. Therefore, claims 2 and 8 also contain the limitation "a sling contoured to the anatomical configuration of the mid-urethra,

proximal urethra, and base of the bladder," as recited in claim 1. Thus, claims 2 and 8 are patentable over Staskin in view of Inman for at least the reasons discussed above.

**2. Staskin in view of Inman does not disclose "wherein the progressively curved shaft is further comprised of a luminous coating," as recited in claim 8.**

The Examiner admits that "Staskin fails to disclose a transfer shaft for a sling having a luminous coating." (Office Action, page 7). As understood by Applicant, the Examiner asserts that "Inman teaches a rod . . . of a transfer instrument . . . having a **reflective** coating." (Office Action, page 7, emphasis added). Applicant respectfully submits that the term "luminous" is not comparable to "reflective."

"Reflective" is defined as "[c]apable of or producing reflection," and "reflect" is defined as "[t]o throw or bend back (light, for example) from a surface." By contrast, luminous is defined as "[e]mitting light, especially emitting self-generated light."<sup>1</sup>

Inman, instead, discloses an "altered light diffraction pattern [on an] otherwise reflective surface of the rod." There is no language in Inman to suggest a luminous coating or any surface that would emit self-generated light. Therefore, Inman does not disclose "wherein the progressively curved shaft is further comprised of a luminous coating," as recited in claim 8.

Thus, claim 8 is patentable over Staskin in view of Inman for at least this additional reason.

In summary, Applicant submits that claim 4 is patentable over Staskin in view of Bilbo for at least the reasons stated above. Applicant further asserts that claims 2 and 8 are patentable over Staskin in view of Inman for at least the reasons stated above. Accordingly Applicant respectfully requests the Examiner to withdraw the rejections under 35 U.S.C. § 103(a).

**Rejection Under Obviousness-Type Double Patenting**

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<sup>1</sup> All definitions herein are from The American Heritage Dictionary of the English Language, Fourth Edition (2006).

The Examiner rejected claims 1-7 on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 3, 6-8, 10, and 11 of U.S. Patent No. 6,808,486. Applicant submits herewith a terminal disclaimer to overcome these rejections. Applicant notes that the filing of a terminal disclaimer is not an admission of the propriety of the non-statutory double patenting rejection. M.P.E.P. § 804.02.

**CONCLUSION**

For at least the reasons stated above, Applicant asserts that claims 1-8, 18, and 19 in the Application are in condition for allowance, and Applicant respectfully requests an allowance of such claims. Applicant respectfully requests that the Examiner call Applicant's attorney at the below listed number if the Examiner believes that a discussion would be helpful in resolving any remaining issues.

Respectfully submitted,

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